

SCOTTISH EXECUTIVE

Health Department

Dear Colleague

MANAGEMENT OF INTELLECTUAL PROPERTY IN THE NHS

The effective management of Intellectual Property (IP) generated by NHS employees has been recognised in recent years as an area of increasing importance. This led to the creation of a technology transfer office for the NHS (Scottish Health Innovations Ltd (SHIL) in 2002.

Guidance published by the Chief Scientist Office in 1998 (MEL(1998)23) applies to the management of IP arising in NHS bodies from NHS funded R&D. IP generated from any source is now to be recognised by the NHS as an asset of value which should be used in the best interests of the NHS and the country as a whole by those best able to do so. The attached Framework and Guidance sets out how this can be achieved for IP to be exploited through commercial channels.

The guidance document is similar to guidance already issued in England, but additionally recognises the role of SHIL in supporting NHS innovation in Scotland and clarifies certain issues raised during extensive consultation by Scottish interests.

Action Required

Chief Executives of NHS Boards should, in consultation with their R&D Lead Officers and HR Directors, ensure that this Guidance is drawn to the attention of all staff and draw up a local implementation plan to ensure that Guidance is applied.

Yours sincerely

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Part 1 - A Framework and Guidance on the Management of Intellectual Property in NHSScotland

Introduction

1.1 This Framework and Guidance is to inform Chief Executives and their senior managers in the NHS and in particular Directors of R&D, Finance, Clinical Operations and Human Resources how Intellectual Property (IP) generated by NHS employees should be managed for the purposes of income generation.

1.2 The White Paper "A Plan for Action, A Plan for Change" recognised the need for the NHS to ensure that its investment in R&D maximises its potential to improve health and health services, and proposed the establishment of a Technology Transfer Office to ensure that innovative ideas from every part of the NHS benefit patients. That Office has been established through the creation of Scottish Health Innovations Ltd. Proper management of new technologies should lead to new products, improved interventions and services for patients and also wider benefits for society as a whole.

1.3 Innovation is not the sole preserve of those involved in R&D, and occurs naturally in the NHS through the work of all its employees. Innovation could be through the delivery or the management of patient care, in the education or training of employees or through the more traditional route of an R&D project. The innovation may, for example, be a novel treatment, a new diagnostic, a device, a new drug or its new use, use of data, software, training material, a treatment protocol, or a new management system.

1.4 Most innovations when they have demonstrated a quantifiable health gain are best brought into use by using normal knowledge management processes and making them freely available to practitioners and managers for the benefit of patients. There are some innovations which can additionally be brought into use through commercial development of new products. There is always IP associated with an innovation, but for an innovation best developed commercially the IP and its professional management is crucial in its realisation. In this document, the employee responsible for the innovation is called the innovator.

1.5 There needs to be wider recognition across the NHS that understanding and protection of IP facilitates rather than impedes uptake of innovations. This Framework and Guidance is intended to provide NHS bodies with the advice they will need to manage the IP generated by their employees. It is recognised that this advice may require to be considered alongside existing local frameworks and that changes will need to be introduced in partnership using existing local Partnership Forums and negotiating arrangements.

1.6 IP has an owner and can be bought, sold or licensed and should be adequately protected. The owner of the IP may or may not be the innovator. The owner of IP can control and be rewarded for its use and by so doing can encourage further innovation bringing benefit to all. The owner of IP has legal rights, although in some cases the owner has to register for those rights to subsist. The principal form of those rights are patents, copyright, design rights, trade marks and know-how.

1.7 In April 1998 the Chief Scientist Office (CSO) published a Policy Framework for the Management of IP arising from Research & Development. The 1998 Policy Framework applies to the management of IP arising in NHS bodies from NHS funded R&D. However IP

is often generated by employees of NHS bodies during the normal course of their duties outside R&D. IP generated from any source is now recognised by the NHS as an asset of value which should be used in the best interests of the NHS and the country as a whole by those best able to do so. This Framework and Guidance sets out how this can be achieved for IP which can only be used by exploiting it through commercial channels.

1.8 Scottish Ministers, with the support of Scottish Enterprise, Highland and Islands Enterprise and a consortium of NHS bodies, have taken an important step in recognising the potential within the NHS by establishing Scottish Health Innovations Ltd. (SHIL). A company limited by guarantee, SHIL has been established with the sole purpose of exploiting NHS innovation, including dissemination throughout the NHS.

1.9 Publication and implementation of this Framework and Guidance is part of the CSO R&D Strategy. CSO has also published a Research Governance Framework for Health and Community Care which sets standards for research and defines mechanisms to deliver them. Protection and exploitation of intellectual property is one of the responsibilities set out within that Framework.

1.10 These steps have been taken against a background of a wider and increasing recognition of the importance of innovation. The DTI White Paper '*Excellence and Opportunity*' A science and innovation policy for the 21st century set out a UK-wide framework for supporting innovation and the inventions that arise from the innovation. An essential aim of this document is to capture and exploit innovations for the benefit of the UK economy. A central element of the DTI initiative is that when an innovation generates income this income may be shared with innovators. The 1998 NHS Policy Framework is fully consistent with this national framework for supporting NHS innovations and innovators.

1.11 Additionally, The Patent Office has published Guidelines for public sector purchasers of research and research providers dealing with IP in Government research contracts. Those Guidelines apply to NHS bodies undertaking R&D and the content of this document is consistent with them.

1.12 The commercial exploitation of IP incurs some cost and some risk. Audit Scotland has confirmed that it will adopt an open-minded and supportive approach to innovation and will support well thought through risk taking in the exploitation of valuable IP. In terms of public sector research, when examining these activities Audit Scotland may address

- whether organisations have adequate procedures in place for identifying and developing outputs with commercial potential
- the extent to which opportunities are identified and explored
- the quality of risk management which adequately assesses risks against potential benefits.
- 1.13 The remainder of this document sets out
 - a Management Framework to ensure that IP generated by all NHS bodies through all their activities, not only from R&D, is now to be managed as an asset. It describes how a NHS body owning IP should manage it, and gives guidance on the use of NHS funds for this purpose.

- Employment Guidance to assist NHS bodies in their application of the Management Framework. It includes general principles of employment conditions for NHS employees and the management arrangements under which they will be expected to operate. It also includes, as an aid, a model insertion into an employment contract and a model entry for a Staff Handbook which can be used by NHS bodies. It will be for NHS bodies to determine how to use and introduce these model documents at a local level.
- A Statement of Partnership which sets out the principles under which the NHS and its funding partners, such as a charity or a university, may treat this jointly owned IP. This has been agreed with Universities UK on behalf of UK universities.

Part 2 - Management Framework

Extension to Existing Policy Framework

2.1 The Policy Framework for the Management of IP under NHS MEL(1998)23 remains operational, but in addition IP generated by a NHS body from activity outside R&D is now included within the management structure set up under NHS MEL(1998)23.

2.2 Under NHS MEL(1998)23 there is a responsibility on NHS bodies in receipt of NHS R&D funding to identify and exploit the IP generated by this R&D. The Research Governance Framework for Health and Community Care states that employers of researchers should ensure that agreements are in place between them and their staff, and between them and research funders, about ownership, exploitation, and income from any IP that may arise from research conducted by their employees; and that employers have a responsibility for ensuring that employees identify, and assist in the protection of, IP. The delivery or support of patient care may also generate IP with significant potential to improve the health service if this is captured, evaluated and then disseminated or exploited. This Management Framework covers this IP in addition to that generated through R&D activities.

2.3 There is no formal responsibility on NHS bodies to capture IP associated with patient care e.g. through audit, but NHS bodies and the employees who generate the innovation will wish to bring it into the same management framework as for R&D.

2.4 Innovation can be used to improve the health service in one of two ways. First, after suitable evaluation, it could be freely disseminated across the NHS by knowledge management processes. Second, the evaluation may show that the innovation has commercial potential and the method of exploiting such potential is the subject of this document. It may not be clear until after evaluation which path an innovation should follow. NHS bodies will need to have in place a management process to undertake such evaluations, with an identified lead person able to respond professionally to the issues raised.

2.5 The formal audit process carried out by NHS bodies to review their R&D outputs (technology audit) may also identify IP that is a 'good practice' innovation which needs to be evaluated and disseminated freely when appropriate. SHIL will act as a portal for the sharing of innovative ideas and a catalyst for utilising technology for a purpose not originally intended.

2.6 Since 1988 NHS bodies have had the power to exploit IP in order to make more income available for improving the health service. The 1998 Policy Framework for IP generated from R&D allowed this income to be retained by the NHS body from within which the IP was generated. NHS bodies are also able to share this income with those responsible, the innovators. These conditions are now extended to IP generated outside R&D, with the IP managed as if it had originated from R&D.

2.7 It is Scottish Executive Health Department policy for an NHS body exploiting IP to retain income from it, and so provide an incentive for the organisation and innovator employees. Income arising from IP can be one-off payments, licence fees or flows of royalties, and such income is generally modest in relation to NHS budgets.

2.8 The statutory power to exploit IP is Section 7 of The Health and Medicines Act 1988. Such exploitation is permitted for the purpose of making more income available for the health service, and this must be the case when an innovation is exploited successfully. It is not always the case that actually maximising income for the individual NHS body is best for the health service. There will always be other strategic priorities to consider such as improving health for the maximum number of patients and providing savings to the NHS. The paramount consideration should be patient benefit; as such, innovations capable of providing health or service improvements to patients across the NHS are as important as those capable of generating income. Those charged with exploiting NHS IP will need to take these considerations into account.

2.9 A further important aim is to capture and exploit innovations for the benefit of the Scottish economy. Funding, through for example DTI and Scottish Enterprise funding schemes, is available to NHS bodies in support of this work.

2.10 NHS MEL(1998)23 applies to NHS bodies and Independent Contractors of NHS Services. Independent Contractors of NHS Services are persons providing services under Part II of the National Health Service (Scotland) Act 1978. Under NHS MEL(1998)23 they share under a contractual arrangement with the NHS Management Executive (now the Scottish Executive Health Department) any benefit derived from exploitation of IP arising from their R&D.

2.11 NHS MEL(1998)23 states that IP should be owned by those best able to exploit it. Generally an Independent Contractor of NHS Services does not have the resources to support the development of IP, or have access to the expertise to exploit it. With research active Independent Contractors increasingly working in collaboration with NHS bodies, it will be those bodies which are better placed to arrange access to the means of exploiting IP. Where the Independent Contractor agrees to a transfer of ownership and the responsibility for the exploitation of the IP to an NHS body, then the requirement to share any benefit with the SEHD will be waived. The transfer of ownership and responsibility for exploitation does not prevent the innovators sharing in the rewards of its exploitation, and all parties are advised to adopt a sharing formula in advance of such transfer and exploitation.

2.12 These extensions to the Management Framework have particular consequences for the exploitation of NHS IP with the potential to generate income. The remainder of this part of the Framework and Guidance describes these consequences and expands on issues introduced in the 1998 Policy Framework. In particular it describes the management procedures that NHS bodies are advised to adopt to exploit their IP.

Management Arrangements for Commercial Exploitation

2.13 Although R&D Offices have a key role to play in identifying IP opportunities, NHS bodies generally do not have the in-house skills to identify and manage IP with the potential to generate income. Development of those complex skills within individual NHS bodies is not cost-effective in the majority of cases because the opportunities identified from the work of a single NHS body would be insufficient. Access to high quality advice is a requirement of good research governance. An NHS body is advised to contract with an external organisation to provide high quality advice on its behalf and to act as an "adviser organisation" to the NHS body.

2.14 In order to provide NHS bodies with a cost effective and expert resource for management of IP, Scottish Ministers, Scottish Enterprise, Highland and Islands Enterprise and a consortium of NHS bodies have supported the creation of Scottish Health Innovations Ltd. (SHIL). This company limited by guarantee has been created with the sole aim of promoting the commercialisation of research, technology and innovations from within NHSScotland.

2.15 In particular, it will

• establish an appropriate infrastructure to support such commercialisation (including arrangements for technology auditing, awareness raising and staff development)

• assess the potential of the IP and support the commercial exploitation of individual innovations and other intellectual property from within NHSScotland on a case-by-case basis

- stimulate the dissemination of new technologies and other innovations across NHSScotland
- promote the technologies and innovations identified by the company in the course of the above activities for the benefit of the Scottish economy generally
- establish close ongoing networks with business support agencies, funders, investors and potential commercial partners

2.16 Being funded by a number of public sources, SHIL does not charge a fee for those NHSScotland bodies it contracts with. In order to maintain its financial viability in the longer term, and to increase the level of funding available for exploitation of NHS innovations, contracts require the retention of a proportion of net income realised from technologies successfully exploited. Being a not-for-profit company, all such income retained will be re-invested in the ongoing work of SHIL.

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2.18 In commissioning IP services from any expert external body – including SHIL and Universities - an NHS body will need to take account of procurement legislation and value for money policy and, in the case of SHIL, the potential loss of future net income. It will need to conduct a competitive tender if the contract value is above any relevant threshold. Procurement should be in line with the Public Services Contracts Regulations 1993.

2.19 The tendering requirement could cover contracting with an external body to provide specialist IP management services in respect of individual technologies **or services more**

generally. Since SHIL does not charge a fee for its services, and will enter into a separate agreement in respect of the income to be retained for each individual technology selected for assistance, the procurement considerations set out above will only apply where the anticipated value of the income to be retained by SHIL in respect of any <u>individual</u> exploitation contract breaches the procurement threshold.

2.20 NHS bodies with existing contracts or agreements should review the terms of their contracts immediately to ensure that they have not inadvertently breached the procurement regulations. In particular, NHS bodies should ensure that the total contract value of general – rather than project specific - agreements are not in breach.

Commercial Exploitation Agreements

2.21 There are three main ways of obtaining income from IP

- outright sale of the IP to an existing company
- licensing or assigning the IP to an existing company in return for up-front fees and/or royalties
- licensing or assigning the IP to a spin-out company set up specifically to exploit the IP in return for fees, royalties or equity.

2.22 Because Scottish NHS bodies are not yet able to form or participate in the formation of companies, or invest in companies for income generation purposes, the equity route in the third of these options is not presently possible. Should the IP be assigned to a company such as SHIL under the second of these options, however, SHIL may itself take equity in spin-out companies.

2.23 Whatever route is chosen an NHS body needs to ensure that the chosen method and the subsequent agreement is in the best interest of NHS patients and that the decision-making process, which will include the management of risk, is transparent and defensible. It is therefore strongly recommended that its adviser organisation should be fully involved in all such considerations and those set out below.

2.24 An NHS body will further need to ensure that its future research and training activities in the subject area of the IP are not unnecessarily or unduly restricted by any agreement. For example an agreement needs to allow the NHS body to retain the right to use the IP for NHS internal research and training purposes. Agreements where the other party is given an option or a right of first refusal to acquire or licence other developments made by the NHS body in the same area are to be avoided. In addition ongoing financial obligations (such as ongoing costs for patents) will normally be the responsibility of the commercial partner.

2.25 Warranty on the validity of the IP should be avoided and no liabilities should be accepted for the quality of the innovation etc. which forms the basis of the IP. There may be some scope for a limited warranty that the NHS body had not previously licensed or assigned the IP in question, but this would need to be rigorously checked through due diligence procedures to ensure that the warranty could be given. Costs which could arise, for example due to patent infringement and product liability, would normally fall only on the commercial partner. Costs of a future research programme and for support of the licence by employees of the NHS body would need to be included in the licence.

2.26 Financial return will be to the NHS body which was the source of the IP. The NHS body through the exploitation agreement should consider whether other NHS bodies could benefit through, for example, preferential terms of sale.

2.27 It is possible that some exploitable items of NHS IP will have an international market and that a licence will cover manufacture and sale in more than one country. NHS bodies entering into licence agreements should seek to include terms that are likely to give patients in developing countries access to products at reasonable cost.

2.28 A commercial exploitation agreement may involve other organisations (e.g. universities) with an interest in the IP. Ownership and management issues for the IP should be clearly defined in a contract with the other organisation agreed well before the commercial exploitation agreement is completed. Guidance on employment and management issues is set out in both the Employment Guidance and Statement of Partnership sections of this guidance.

2.29 Patient biological samples may also be obtained by NHS employees of NHS bodies during the course of their duties in delivering patient care or in carrying out R&D. Fully informed consent for all intended purposes should be obtained if it is anticipated that such biological samples might be used in research, whether immediately or in the future. If subject to such consent an NHS body transfers these samples for further research, e.g. to a university, then it is appropriate to seek a share in any benefit obtained by subsequent exploitation on previously agreed terms.

2.30 Transfer of biological samples may be to a third party, allowing the third party to carry out research (in its own right or on behalf of an NHS body) or to enable the third party to evaluate the materials for possible licensing arrangements. The third party could be a university, a public sector research establishment or a commercial organisation. Transfer of materials, which would be dependent on appropriate written consents being obtained, should be according to terms of a Materials Transfer Agreement between the NHS body and the third party and which should be entered into before the material is transferred. The NHS body may have rights in the material which need to be protected and these rights might be lost or compromised by the transfer unless an agreement is made which makes appropriate provision. NHS bodies should therefore take the advice of their adviser organisation on the IP aspects of a Materials Transfer Agreement.

Income from Commercial Exploitation

2.31 Income from successful commercial exploitation of IP, through sale or licensing of IP, will normally be received by an NHS body or through its adviser organisation. In achieving this income, the NHS body and the adviser organisation may have incurred expenditure for patent or legal work and it is normal to recover this expenditure as a first charge on the income. The net income, after deduction of these costs, would then be shared between the adviser organisation and the NHS body responsible for generating the IP. Normally the adviser organisation will receive between one quarter and one third of the net income, but this could be larger if the adviser organisation also provides funding to further develop the IP.

2.32 The residual income will go to the NHS body from which the IP was generated. Apart from the statutory exception noted below, there is generally no legal requirement for an NHS body to share the income it owns with an employee (the innovator) who created the IP in the course of employment or normal duties. However, to give an incentive to the innovator to support the exploitation process a reasonable share of the innovator with a flat one third of the net income (with the remaining 2/3rds going to the innovator's department and their NHS body), others operating on a sliding scale designed so that the proportion paid to the innovator falls as the level of income rises (see Baker Report). Each NHS body should agree its policy on income sharing and make it known, as discussed fully in the Employment Guidance section. The innovator can decide whether to take the income as a personal benefit. Where sharing schemes reward the innovator a share of about one third of the residual income.

2.33 The statutory exception referred to above relates to the provisions of the Patents Act 1977. An employee whose innovation belongs to the employer and in respect of which a patent has been granted may apply to the Court or the Patent Office for compensation if the patent proves to be of 'outstanding benefit' to the employer.

2.34 Income from the successful exploitation of IP is often derived from R&D undertaken collaboratively with universities or other NHS Bodies. NHS bodies for which this is likely to arise should take care in setting their reward structures to ensure, as far as possible, that their employees have sharing arrangements similar to those of collaborators.

2.35 When IP arises from collaborative work with universities it is normal for employees of both organisations to have contributed to the generation of the IP. This is discussed more fully later this document, but it could be decided that the university rather than the NHS adviser organisation is best placed to handle the IP. If so the university would be entitled to recover a proportion of the net income to cover costs incurred and the residual income would be shared between the university and the NHS body as previously agreed. If the adviser organisation handles the IP then the residual income would be shared with the university, again as previously agreed.

2.36 Royalty rates will vary from case to case, negotiated between the adviser organisation representing the NHS body and the outside organisations responsible for exploiting the IP. An especially successful exploitation may result in an NHS body receiving considerable residual income (revenue or capital).

Accounting for Income, Expenditure and Losses

2.37 As set out in paragraph 2.7 above, NHS bodies are able to retain the income generated from IP. It is normal practice to reward in some way the unit that generated the IP, with the remaining surplus used generally to improve the health service. This can include further investment in IP. IP-related income, expenditure and surplus or deficit should be disclosed separately in annual accounts if they are material.

2.38 There is no guarantee that any filed patent, or any other item of IP, will bring a return to the NHS. In the event that an item of IP turns out to be worthless, or have a value lower than the balance sheet carrying value, then the asset and the costs of its management will be deemed to be 'impaired' and the fall in value should be taken to the income and expenditure account of the NHS body for that year.

2.39 Such a possibility should not, however, reduce the commitment of NHS bodies in identifying opportunities which could bring benefit to the NHS, or in managing these opportunities appropriately.

Part 3 - Employment Guidance

Introduction

3.1 The Policy Framework for the Management of IP in NHS MEL(1998)23

- informed NHS bodies that ownership of IP may require explicit recognition in contracts of employment of their employees
- drew attention of NHS bodies to the need to agree a policy on ownership of IP for employees holding joint appointments with universities or for employees engaged in R&D away from their place of employment
- recognised the need to provide an incentive to NHS bodies for the appropriate and cost-effective exploitation of IP by allowing them to retain income generated and to establish schemes to share this income with their employees.

3.2 The Research Governance Framework requires NHS bodies employing researchers to ensure that agreements are in place between them and their employees, and between them and research funders, about ownership, exploitation and income from any IP that may arise from research conducted by their employees. Employers also have a responsibility for ensuring that employees identify and assist in the protection of IP.

3.3 The Policy Framework under NHS MEL(1998)23 is now extended to cover IP derived from the management or delivery of patient care and, as for IP arising from R&D, this calls for agreements with employees.

3.4 Dealing with IP in contracts of employment can be complex, but without such provision there will be uncertainty, when IP does arise, over its legal ownership. The employee will also need to know how the NHS body intends to manage an item of IP and what personal reward will be available if the IP is exploited successfully to produce income.

3.5 This Employment Guidance is to help NHS bodies act correctly in conforming with research governance requirements and with the Management Framework section of this guidance and making these issues known to employees. It also provides advice on related contractual arrangements entered into by those working in some way for the NHS.

3.6 It is recognised that there are two significant types of employment situation in this area:

- The first relates to those employees for whom research is part of their duties or more generally where patentable inventions might reasonably be expected to arise from their duties. In either case this expectation should be confirmed on a contractual basis.
- The second situation relates to employment outwith the above areas where the potential to innovate, or discover opportunities which may generate income or have financial implications for the NHS, might be less clear.

3.7 It is considered important for NHS bodies to consider very carefully at a local level which employees or posts the revised IP contractual arrangements should be applied to and

how best to implement any contractual changes, utilising local partnership and negotiating arrangements as appropriate. It may also be appropriate to agree a future date from which any new employees entering a relevant post are automatically issued with a revised contract of employment incorporating the IP requirements.

3.8 This Employment Guidance is for NHS employees, although Independent Providers of NHS Services may find the content useful in agreeing how to deal with IP in their organisation.

3.9 IP generated by NHS employees, often employed under complex arrangements, has potential commercial value. The advice in this Employment Guidance is <u>not</u> a substitute for appropriate legal advice.

Employment Conditions: General Principles

3.10 IP is the generic term for a diverse range of rights including patents, copyright, trade marks, design rights, and know-how. The owner of IP has exclusive rights to license others to carry out certain agreed activities or to exploit an innovation commercially. As a result IP is of commercial value to its owner and so it is important that IP generating organisations properly provide for its regulation and protection.

3.11 It has been rare for the employment contracts of NHS employees to include provisions for IP. Without clarity on ownership and other issues, confusion and conflict often arise. There is a risk that inconsistent and inappropriate employment conditions may be introduced. Employees sometimes believe they have rights in IP which they do not. The complexity of this area means that there are many benefits to be gained by confirming the statutory position in writing between employer and employee to avoid future disappointment. It is one purpose of this document to provide model employment conditions to which NHS bodies can refer.

In the absence of express contractual provision, ownership of IP is determined by 3.12 statute. Generally speaking, under statute an employer will be the owner of IP generated by an employee in the course of normal duties of employment unless the employer and employee have agreed otherwise. Such an agreement does not have to be in writing and can have arisen through custom and practice. Any agreed custom and practice should ideally be reflected in writing in the contract of employment. Where there are no contrary agreements then this should be stated expressly in the contract. However for patentable inventions there are additional conditions which must be met in order for the employer to own the rights to the invention. Not only must the invention be made in the course of normal duties, or in the course of duties falling outside the normal duties but specifically assigned to the employee, but it must also have been reasonably expected that an invention may result from such duties. In addition when looking at patentable inventions the employer, not the employee, will be the owner where the invention is made by the employee in the course of duties which, because of their nature and particular responsibilities, imposed on the employee a special obligation to further the interests of the employer NHS body.

3.13 Deciding legally whether an invention might reasonably be expected to be made in the course of normal employee's duties has proved difficult in the past. For NHS employees

engaged in R&D, patentable inventions made in the normal course of duties might reasonably be expected to arise from these duties and ownership would be with the NHS body. If the process used NHS resources as would be normal then the NHS body might have a stronger claim to ownership of the IP. For NHS employees delivering patient care, or indeed employed in some other capacity, it will be a question of fact as to whether inventions might also be reasonably expected from these duties. Where this is the case, new terms of contract should make it clear that making and reporting innovations and inventions is part of the employee's duties. An agreement to keep such innovations and inventions confidential should also be entered into. It is for NHS bodies to identify, in partnership, the relevant posts, employees or group of employees for whom it would be necessary to apply revised contractual arrangements.

3.14 In order to bring all NHS employees into the IP Framework and Guidance and to avoid detailed discussion on ownership, **i** is recommended that the NHS should offer reward on the same basis to all NHS employee innovators, in return for assignment of IP to the NHS body when that is necessary. In this way innovations of value can have the best chance of being exploited and deliver an improved health service. Bringing an innovation into practice is a complex task which should be carried out by those best able to do so.

3.15 Under certain circumstances there is a statutory procedure whereby the Court or Patent Office may order an employer to reward an employee inventor. Scottish Executive Health Department policy is for an NHS body to share with its employees the benefit derived from any successful exploitation of IP generated by those employees where it is owned by that body. Employees who are prepared to sign, or have already signed, amended employment contracts containing revenue sharing arrangements may already be in a position to benefit. Each NHS body needs to agree a sharing scheme and to inform its staff. Examples include a simple 1/3 distribution between innovator, unit and the NHS body, or a sliding scale depending on the value of net income.

3.16 It is especially important that NHS bodies communicate to all their employees via a section within the Staff Handbook, or equivalent, and regular awareness raising, that all staff who generate IP will be subject to the revenue sharing arrangements in place. This is vital in order that those staff not automatically covered by a signed contract variation or existing contract are under no doubt as to the position should they find themselves in this situation. The position being that they forego ownership by assigning all IP to the NHS body which employs them.

Model Employment Conditions

3.17 The model employment conditions attached as Appendix 1 are intended to be suitable for all appropriate existing and new NHS employees. They include recognition that the NHS is a research-based organisation, committed to the application of best practice and providing a creative environment in which employees can work. Advice on amending existing local employment contracts is given below. NHS bodies may wish to use their own form of words within the context of their own employee contracts. The commitment to revenue sharing (see above) is within the model employment conditions.

3.18 NHS MEL(1998)23 includes copyright as one of the categories of IP owned by the NHS body when arising in the course of an employee's employment. In order to encourage

employees to publish freely in academic or professional journals or through an electronic medium, NHS bodies will normally assign to the author the ownership of copyright in any work to be published and will waive any claim to financial benefits arising from the publication. However the NHS body will need to secure within the employment contract a world-wide, irrevocable, royalty-free licence to use such a work for its own non-commercial purposes (e.g. training, further research) as a condition of the assignment. Otherwise, once assigned, the NHS body will have no further rights in relation to that work as it will have transferred ownership to the author.

3.19 There are some items of copyright (e.g. training material, patient information leaflets, software, design drawings) which the NHS body will wish to retain and not to assign. The issue of copyright is addressed specifically in the model employment conditions and further in the model management arrangements.

Jointly Appointed or Managed Staff

3.20 In addition to employees whose payroll costs are met entirely by the NHS, there are many who hold joint appointments where part of their payroll costs are partially or totally funded by another party (e.g. a university, a medical charity, a commercial sponsor). Sometimes an NHS body uses its own funds to support an employee in a university (e.g. through distinction awards) with the employee holding a university contract. Normally the employer holding the employment contract would own the IP with a commitment to share the benefit e.g. royalties with the other party. This is only a starting point, is insufficient by itself to decide ownership and individual consideration will often be necessary. Factors which affect a decision include consideration of the source of funding for the post and the resources used to support the post including the use of NHS patients. For such employees holding an NHS contract, the model employment conditions for dealing with IP owned by the NHS would be appropriate if agreed with the other party.

3.21 It is appropriate that revenue sharing and income streams relating to work resulting from joint appointees be agreed by the joint employers. Factors to be taken into consideration in agreeing these include

- proportion of funding and other resources from each party, including access to NHS facilities and equipment and involvement of patients
- IP management resources provided by each party
- ownership of background IP.

3.22 If it is concluded that ownership of IP generated by an employee with a joint appointment will not **I**e with the NHS then the contractual conditions between the parties would normally include

- a commitment to share benefit with the NHS body;
- a commitment to use best endeavours to exploit this IP and keep the NHS body advised of progress;
- return of the IP to the NHS body by means of an assignment if the other party fails to exploit within a reasonable period and the NHS body so wishes, and
- a commitment to acknowledge the contribution of the NHS in any publication.

3.23. IP of potential commercial value arising at the NHS/University interface can be generated by an employee holding joint appointments or by employees holding individual appointments with the two bodies. This IP can be generated through R&D or by the delivery of patient care. Discussion on ownership, management and benefits can be complex and a simple starting point can be to agree joint ownership of the IP with one party having exploitation rights, and to share equally the cost and the benefit. Equal shares, for example, might typically be the starting point for IP arising from R&D within a NHS/university collaborative programme under the NHS Priorities and Needs R&D arrangements, but subject to variation where the parties agree that equal shares are inappropriate.

3.24 When an honorary contract purely recognises the research status of a NHS employee or the NHS service status of a university employee, such a contract would not be expected to affect the ownership of IP, it should continue to belong to the organisation holding the substantive employment contract. Where the NHS funds a university appointment which includes specific NHS service provision, the provisions of paragraph 3.20 above would be expected to apply.

Other Circumstances

3.25 The NHS carries out R&D in which costs are often jointly met by charities, universities and the NHS. A Statement of Partnership on IP which sets out the principles under which the NHS and its funding partners can treat IP arising from R&D they jointly fund is attached.

3.26 An NHS body sometimes acts under contract as host to employees from another organisation or the body seconds its own employees to another organisation. Any IP arising from those employees will vest in the employer organisation unless otherwise agreed between the parties. In all such cases, the NHS body would need to agree in a contract with this organisation how IP is to be managed and who will own it. It is normal for the NHS body to seek ownership of the IP where appropriate (by means of an assignment from the other organisation if necessary) but whether or not it owns the IP it would always aim to share benefit from successful exploitation.

3.27 Agreement on the management of IP needs to be reached between parties, whatever the arrangement, before any employment begins and considered routinely in any joint-appointment, host or secondment agreements whether or not it is judged likely that IP will be generated during the course of that employment.

3.28 Senior academics in medical schools who hold honorary contracts with a recognised NHS employer sometimes receive an additional contribution to salary (a distinction award) in recognition of outstanding professional work of wider benefit to patient care in the NHS as a whole. This work can include R&D, or innovation and improvement in the service. NHS bodies will wish to agree formally with the university how any derived benefit should be shared when NHS resources are used to generate exploitable IP.

3.29 Employees may have a part-time NHS contract and be self-employed part-time (for example in private practice). IP arising through the NHS contract work will be owned by the NHS (generally speaking and subject to the patent proviso set out in paragraph 3.12 above), and IP arising from work undertaken by the employee which is unconnected with the normal

course of NHS contract duties will be owned by the employee. However the situation is often less clear cut with the self-employed work undertaken overlapping the NHS contract work. In such circumstances any IP arising may be owned by the NHS body if it is construed to relate to the duties under the NHS employment. If there are special circumstances which make it more likely for that IP to arise within the self employment, the NHS body may agree with the employee revised terms for the sharing of benefit. To avoid such confusion it is advisable that any appointment under a part-time NHS contract includes clear provisions for what is expected of the specialist appointee and what exactly is expected to flow to the NHS body from that appointment.

3.30 An NHS body often acts as a host for training purposes during which IP might be generated. For the purposes of IP management it is advisable to treat the trainee within the training agreement as an employee of the NHS body and subject to the management arrangements of the NHS body. A trainee may not be an 'employee' for the purposes of the statutory provisions regulating IP. It is therefore advisable that specific provision is made within the training contract for ownership of any IP rights generated to vest in the NHS body. It is important that this issue is dealt with routinely before the trainee starts in a fair, reasonable and clear contract. If the trainee is employed by a third party then agreement with this employer will be necessary to ensure that IP created by the trainee can belong to the NHS body.

3.31 For other third parties who are not employees of an NHS body, but who generate IP on its behalf, the statutory provisions mean that the NHS body will not automatically own such IP. Instead the author or innovator will own the IP rights in their work or invention or, if they are employed by another body or have otherwise agreed to it, then the IP will be owned by that body. This situation usually arises in relation to individuals who are employed as consultants and with whom there is therefore a consultancy contract rather than a contract of employment. It would be normal for the NHS body to wish to retain the IP rights in the output of the work, and for this to be stated within the contract of engagement.

3.32 An NHS body may contract with a third party such as a charitable or voluntary sector organisation or a private health care organisation to provide services to NHS patients. Also Scottish Ministers may provide funds to charitable or voluntary sector organisations to support R&D. As mentioned above, any IP generated from this work would normally be owned by the organisation which employs the person who generates the IP unless there is an agreement to the contrary between the commissioning authority and the third party service provider.

Guidance for Contracts

3.33 The model employment conditions set out in Appendix 1 provide a template for new contracts of employment.

3.34 The Research Governance Framework requires NHS bodies to have agreements in place with their employees on the management of IP. Where there are existing employees whose contracts do not deal with the ownership of IP, NHS bodies will wish to take appropriate steps to ensure that all staff are made aware on appointment via a Staff Handbook insertion of the position with IP and its ownership by the employing body and any sharing arrangements applicable locally. Steps should also be taken to communicate to all other

existing staff this same information. It is also recommended that this communication occurs on an annual basis in order that all NHS employees are always aware of the position in respect of IP. As stated previously in this guidance any contractual variations should be introduced in Partnership utilising local Partnership Forums and negotiating arrangements as appropriate.

3.35 The model conditions on the whole reflect the current legal position on IP and have been prepared to cover the two employment situations described in paragraph 3.6 above.

Management Arrangements: General Principles

3.36 An NHS body will wish to inform its employees, or to have available on request, its arrangements for dealing with IP of value. These arrangements will include

- general management arrangements in the organisation;
- particular arrangements for employees engaged in R&D;
- arrangements for sharing with employees the rewards from commercial exploitation, and
- special conditions concerning copyright.

3.37 The Staff Handbook, or equivalent, is seen as the most appropriate vehicle for this information.

3.38 General management arrangements would set out who in the NHS body has the responsibility for dealing with IP issues and the responsibilities of employees within these arrangements.

3.39 An NHS body engaged in R&D has obligations within the Research Governance Framework to identify IP of value arising from this R&D and to exploit it. The responsibilities that this obligation implies for employees need to be set down. In addition, employees engaged in R&D sometimes undertake work under contract which is funded by an external sponsor. Procedures for dealing with IP within these contracts will need to be made known to employees. Each NHS body will need to decide formally how rewards derived from commercial exploitation of IP are to be shared between employees and the organisation.

3.40 Effective management of IP by a NHS body will usually include establishing agreements with partner universities on how IP generated through joint work, in particular R&D, is to be managed. These agreements will need to be negotiated using the content of this Employment Guidance as a basis.

3.41 The model management arrangements are given here at Appendix 2 and intended as a model entry for a Staff Handbook. It is only guidance and may be modified as appropriate by an NHS body, except to the extent that the Staff Handbook has contractual effect. It will need to include details of the specific revenue-sharing scheme agreed formally by the NHS body.

3.42 Each NHS body will wish to decide its strategy for informing employees of these new arrangements. All employees would need to receive a summary of the management

arrangements and new employees should receive this information as part of their induction process.

3.43 As it would be the normal practice to issue a Staff Handbook and provide induction material only to new staff, local systems will need to consider the most effective way of making all staff aware generally of the position in respect of the management of Intellectual Property. This will ensure that all NHS employees, including those who do not require a specific contractual requirement as a result of the post they hold, do have an awareness of the expectations on them as NHS employees should they find themselves in the position of discovering or generating an innovation. Obviously, it will be for local systems to determine the best way of achieving this and it is suggested that Appendix 2 could be summarised in some way for ease of circulation to staff by a method determined by local management in Partnership with local Partnership Forums.

Part 4 - Statement of Partnership on Intellectual Property

Introduction

4.1 CSO introduced in July 1998 a new policy framework under NHS MEL(1998)23 for the management of intellectual property (IP). This document is a Statement of Partnership on IP which sets out the principles under which the NHS and its funding partners should treat IP arising from R&D they jointly fund. For these purposes R&D means work which is intended to produce new knowledge which is generalisable and which is planned to be widely disseminated.

4.2 CSO recognises and values the fact that much of the R&D it supports and from which IP is likely to arise is funded jointly by CSO and others including universities, statutory research councils, registered charities, government Departments and the European Commission. It also recognises that many of those who carry out R&D under contract from CSO are employed by a university or jointly by a university and a NHS body.

4.3 Most universities already have in place their own arrangements for the management of IP they generate from their research, including the sharing of any resulting benefit which may arise with their employees. The NHS policy framework has many similarities to the practice adopted by universities including sharing of benefit with those carrying out the R&D for the NHS.

4.4 NHS bodies meet the costs they incur by their involvement in R&D funded by their research partners. Where this R&D generates IP, ownership and the management of this IP should be addressed in the R&D contract. The research partner will recognise in the contract that the NHS body could be a contributor to the generation of this IP even if the contract for the R&D is placed with a partner university. The research contract should recognise the NHS body as a beneficiary in the event that the IP has commercial value.

Mutual Obligation of NHS Bodies and Universities

4.5 When IP is generated by joint R&D between NHS bodies and universities, for example by individuals holding joint appointments, then the organisations together should decide

- who owns the IP
- who is to manage the IP and how costs are to be met
- how any derived benefit is to be shared.

4.6 The purpose is to ensure an outcome which will be fair for both organisations and their employees and lead to the greatest return. Such arrangements should operate even if the originator of the IP (the innovator) is solely employed by one organisation. It is often the case that the other organisation makes an indirect contribution to the employment costs as well as a direct contribution to the research costs and so contributes to the development of the IP.

4.7 Both parties should endeavour to agree ownership and details of revenue sharing well before any financial benefit is derived, preferably at the initial employment contract or research proposal stage.

4.8 Considerations of the organisations leading to a decision on ownership should include

- employment status and sources of funding of the innovator
- contribution to funding of the R&D activity by each party
- contribution to and ownership of background and foreground IP.

4.9 In making the decision the organisations should recognise that if they agree joint ownership of IP with commercial value then one organisation should be given exclusive rights to exploit.

4.10 The party given the exclusive right to exploit the IP should enter into an agreement with the other party which should include

- a royalty-free licence to the other party allowing use of the IP for further research
- a commitment to use best endeavours to exploit this IP and keep the NHS body advised of progress
- a commitment to share benefit on fair terms
- an agreement to offer assignment of the IP if the party owning the IP fails to exploit within a reasonable period.

4.11 Management of IP, including the responsibilities for meeting the costs of exploiting the IP, should be agreed by both parties.

4.12 It is by no means certain that any IP will be successfully exploited, but when it is the parties should agree how the benefit, less the costs of exploitation, will be shared between them. Considerations should include the contribution of each party in its support of the research and the researchers.

4.13 It is expected that the parties will wish to adopt similar revenue-sharing agreements with their innovators so that there is no financial advantage or disadvantage resulting from employment status.

Benefits of the Partnership

4.14 It is in the mutual interest of CSO and its funding partners for the IP arising from R&D they fund to be well managed. The funding partners collectively recognise it to be a valuable asset.

4.15 It is also in the mutual interest of NHS bodies and the universities that they establish a partnership in the identification and management of IP which values the contribution made by each party. The extent of the joint R&D activity requires each to be a responsible partner, maintaining confidentiality where necessary, so that maximum benefit is derived by both parties. The introduction of IP management by the NHS will contribute to a responsible partnership.

4.16 It is important to universities that the NHS is treating IP as a valuable asset. NHS bodies are required to set-up processes, as a condition for receipt of R&D funding, which continue to identify IP as it is generated. Because of the joint nature of much of the work this will lead to exploitation opportunities which will have benefits for both partners.

Model Employment Conditions

Appendix 1

Although the employing body in these model employment conditions is referred to below as 'the NHS Board', they are intended to be appropriate to employees of all NHS bodies and to be of interest to Independent Providers of NHS Services.

Introduction

1. The NHS Board management procedures for intellectual property (IP) have been approved by the Board and are available on request. The procedures are consistent with the Management Framework for IP of the Scottish Executive Health Department.

2. The NHS Board policy is to encourage and enable employees to participate in the generation and exploitation of IP as part of its commitment to delivering the best possible patient care. Sometimes an improvement to patient care can best come about by the protection of the IP and exploiting it commercially rather than by immediate widespread dissemination. The policy is to maintain a balance between the legitimate needs of the NHS Board to protect its interests, and the provision of a creative environment for employees to work where innovation and excellence are rewarded. The NHS Board has therefore agreed that

- (i) income generated by successful exploitation of its IP and received by the NHS Board will be shared with the innovator(s) on an agreed sharing basis
- (ii) the NHS Board will assign to its employee the copyright in any article produced by the employee intended for publication in an academic or professional journal and with no commercial value, in which event it will waive any claim to financial benefit arising from the publication unless specifically agreed otherwise. The NHS Board will however retain a world-wide, irrevocable, free licence to use the publication for its own non-commercial purposes, including research and training.

3. In this context, an innovator is defined as the person without whose intellectual contribution the development would not have taken place.

Ownership of Intellectual Property

4. From time to time during the normal course of employment you as an employee may generate IP which may have value in the delivery of better patient care. This IP can be in the form of inventions, discoveries, surgical techniques or methods, developments, processes, schemes, formulae, specifications, or any other improvements which may give rise to certain rights such as patents, trade marks, service marks, design rights, copyright, know-how, trade or business names and other similar rights (all of the foregoing rights being referred to as 'Intellectual Property Rights').

5. Where such IP is created in the course of your employment or normal duties then under UK law it will generally belong to the NHS Board, unless agreed otherwise in writing between you and the NHS Board. In relation to inventions potentially subject to patent protection this applies only if the duties of your employment would normally have been expected to give rise to inventions or if the nature of your responsibilities and duties are such that you are under a special responsibility to further the interests of the NHS Board. It is a condition of your employment not to exploit any IP Rights without the specific approval of [insert the job title of the relevant officer]. In addition you are also required to give the NHS Board all reasonable assistance required by the NHS Board in order to give full effect to this clause.

Confidentiality

6. Research outputs and resulting IP often represent a considerable investment by the NHS Board and are potentially of significant value to the NHS Board. You should treat as confidential and not disclose to any third party any research results or other information of a confidential nature in respect of any innovation, whether your own or a colleague's, without prior written approval of the NHS Board. For the avoidance of doubt the requirement to obtain this approval applies to submission of theses publication and papers, abstracts or for grant proposals.

Model Management Arrangements: Model Entry to a Staff Handbook

General Management Arrangements

1. These management arrangements apply to NHS bodies. They can also apply to employees of Independent Providers of NHS Services, except that if these Providers undertake to exploit their intellectual property (IP) outside arrangements entered into with an NHS body they will be required to share benefit with the Chief Scientist Office (CSO) on terms to be agreed. This applies when the IP arises from R&D funded by the NHS or if NHS resources are used to transfer into practice IP arising through the delivery of patient care. For convenience, the employing body is referred to below as 'The NHS Board'.

2. The NHS Board recognises that from time to time, during the normal course of employment, an employee may generate IP which may have value in the delivery of better patient care. IP (patents, copyright, design rights, trademarks, know-how) which arises in, or could reasonably be expected to arise from, the course of the normal duties of an employee undertaking R&D normally belongs to the NHS Board, unless an existing contract with either the employee or with another party (such as an external sponsor) overrules.

3. For employees generating IP outside R&D, particularly patentable IP, it is not always clear where ownership lies. However, in return for assignment of the IP to the NHS Board, the NHS Board will offer employees the same potential benefit as to others where ownership by the NHS Board is more clearly defined. The NHS Board will then undertake to evaluate and exploit the IP when appropriate.

4. The NHS Board also recognises that some of its employees hold employment contracts funded jointly by the NHS and another party, or funded entirely by another party (e.g. a university, a medical charity, a commercial sponsor). Others are fully employed by a university but receive a supplement to salary from the NHS. The NHS Board will agree and thereafter formalise with the other party how IP generated during the employment is to be managed to the maximum benefit of the NHS Board and the employee.

5. An NHS Board employee may have a part-time NHS contract and be employed parttime elsewhere (for example in private practice). If IP arises during this period of NHS employment it will normally be owned by the NHS Board if it is construed to relate to that employment. If there are circumstances which make it more likely for the IP to arise within the self-employment, then the NHS Board may agree with the employee alternative terms for the sharing of benefit and will set these out in an agreement.

6. An NHS Board employee may have an honorary contract with another organisation e.g. a university which recognises the research status of an employee. IP generated by such an employee will normally be owned by the NHS Board. Ownership of IP in other honorary contracts will need to be agreed as described in paragraph 4 above.

7. IP generated by an employee acting outside their NHS duties will be owned by the employee subject to the terms of employment set out above.

8. NHS Board policy is to encourage and enable an employee to participate in the generation of IP as part of its commitment to encourage innovation and to deliver the best possible patient care. Sometimes an improvement to patient care can only come about by the protection of the IP rather than by immediate widespread dissemination. The policy is to maintain a balance between the legitimate needs of the NHS Board to protect its interests and the provision of a creative environment for employees in which to work. The NHS Board has agreed that income generated by successful exploitation of IP can be shared with the inventors, the employees responsible for the innovation.

9. Any employee wishing to discuss the protection of any idea or other form of IP should discuss the matter with [the R&D Manager] at the earliest opportunity and, in any event, before disclosure of the idea to any party outside the NHS Board, either orally or in writing. Prior public disclosure (other than under explicit terms of confidentiality or to another employee of the NHS Board) may invalidate any subsequent patent application and diminish both potential commercial value and benefits accruing to the NHS Board and the inventor. It is essential therefore that ideas and inventions are not generally discussed and are reported instead through the correct channels. All employees should be aware of the importance of avoiding improper disclosure of their inventions and those of others.

10. A record will be kept of the date and time on which an employee reports to [the R&D Manager] that he or she is the inventor of a creative product. Employees are reminded of the importance of keeping accurate and dated laboratory notebooks so that, in the event of similar IP being generated elsewhere, the ownership of the invention can be legally attributed. Such notebooks can be important when applying for patents in the USA and also for identifying know-how.

11. [The R&D Manager] will be the initial contact point for advice, and can provide details of the support available for the management of IP

12. The NHS Board maintains a register of all IP rights owned by the NHS Board which have been licensed or assigned to a third party where an employee is a named inventor or originator. Details of these IP rights and the income they generate will be given to CSO from time to time on request.

13. The NHS Board is the vehicle for holding patents and other IP, but is free at its absolute discretion to engage another party (e.g. an independent company) to exploit its IP on its behalf.

14. The NHS Board has arrangements in place for the exploitation of IP. Advice will be available to decide ownership and transfer of IP to the NHS Board when this is agreed to be necessary. Without transfer of the IP, NHS resources will not be available to the employee to exploit the IP. Employees should take no steps to exploit any NHS Board IP without the specific approval of the NHS Board. Employees are expected to co-operate with those charged by the NHS Board to execute its management responsibilities.

15. Currently [insert the NHS Board agreed percentage] of the income received from IP by the NHS Board is distributed to the employee(s) who is the inventor of the IP. It is at the discretion of the inventor to agree to share this income with others if appropriate. Income is

income received by the NHS Board after the deduction of any reasonable expenses incurred by the NHS Board in achieving the income (including patent and legal expenses).

Particular Arrangements for Employees Engaged in R&D

16. [The R&D Manager] will from time to time arrange for an audit of NHS Board R&D activity to satisfy CSO requirements for identifying potential IP of value. Employees are required to co-operate fully with this activity.

17. Employees will sometimes be engaged in contracts for R&D which are funded wholly or in part by external sponsors (e.g. universities, medical charities, industry). These contracts will ensure that adequate provision is made for the ownership and the exploitation of arising IP with the NHS Board retaining or obtaining ownership when appropriate. Employees should ensure that they understand their position and their obligations within these contracts, taking their own independent advice as necessary.

18. Employees engaged in R&D will sometimes engage in discussions with external organisations on funding R&D. Employees are reminded that it is the NHS Board's responsibility to agree a price for carrying out this R&D, and in fixing this price the NHS Board will pay due regard to the IP which is likely to result from the contract.

Special Conditions Concerning Copyright

19. Statute provides that copyright in any work produced for the NHS Board by an employee in the normal course of employment belongs to the employer. The NHS Board will normally assign to the author copyright in a work intended for publication in a professional or academic journal or electronically, and waive any claim it may have to benefits arising from the publication. The NHS Board however reserves the right to itself at no cost to reproduce and use these publications for its own non-commercial purposes, including for research and training. The NHS Board does not assign any of its other copyright to the author including, without limit:

- (i) course or training materials or patient information leaflets produced by an employee in the course of employment for the NHS Board and which are produced, used or disseminated within or outside the NHS Board.
- (ii) any software program generated by an employee in the normal course of their employment
- (iii) any designs, specification or other works which may be necessary to protect rights in commercially exploitable IP.

however, the NHS Board does support the right of identification of author(s) for a copyright work.